



US009220904B2

(12) **United States Patent**
Mower

(10) **Patent No.:** **US 9,220,904 B2**
(45) **Date of Patent:** **Dec. 29, 2015**

(54) **SYSTEM AND METHOD FOR TRIGGERING
CONDITIONING OF THE HEART USING THE
INTRINSIC HEARTBEAT**

(71) Applicant: **MR3 Medical, LLC**, North Oaks, MN
(US)

(72) Inventor: **Morton M. Mower**, Avon, CO (US)

(73) Assignee: **MR3 Medical, LLC**, North Oaks, MN
(US)

(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 0 days.

(21) Appl. No.: **14/285,715**

(22) Filed: **May 23, 2014**

(65) **Prior Publication Data**

US 2014/0350628 A1 Nov. 27, 2014

Related U.S. Application Data

(60) Provisional application No. 61/826,724, filed on May
23, 2013.

(51) **Int. Cl.**
A61N 1/00 (2006.01)
A61N 1/368 (2006.01)
A61N 1/362 (2006.01)

(52) **U.S. Cl.**
CPC **A61N 1/368** (2013.01); **A61N 1/3628**
(2013.01)

(58) **Field of Classification Search**
CPC **A61N 1/3627**
USPC **607/4, 5, 18, 17**
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

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Primary Examiner — Theodore Stigell

Assistant Examiner — Nadia A Mahmood

(74) *Attorney, Agent, or Firm* — Oblon, McClelland, Maier
& Neustadt, L.L.P.

(57) **ABSTRACT**

A rules engine acquires sensor data from sensors applied to
the heart and detects an intrinsic beat of the heart. The rules
engine determines whether an electrical waveform should be
applied to the heart and, if so, the type of electrical waveform.

8 Claims, 2 Drawing Sheets

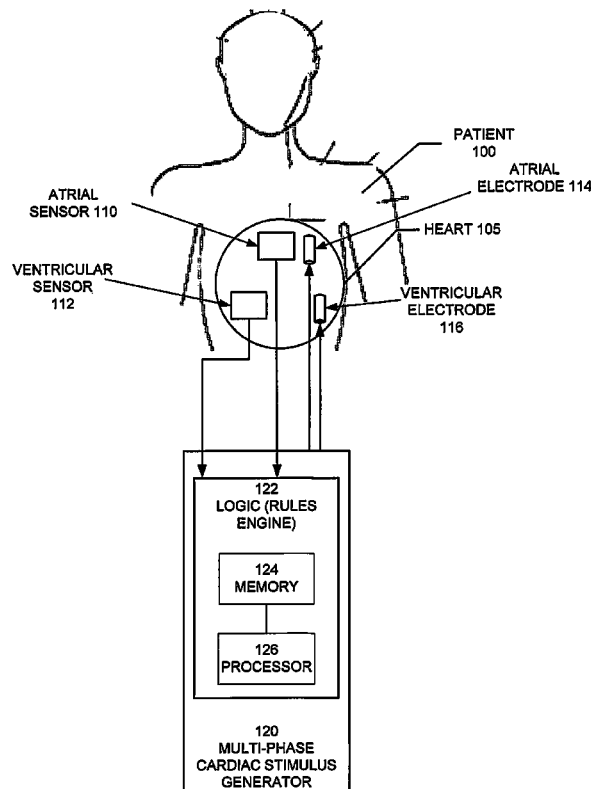
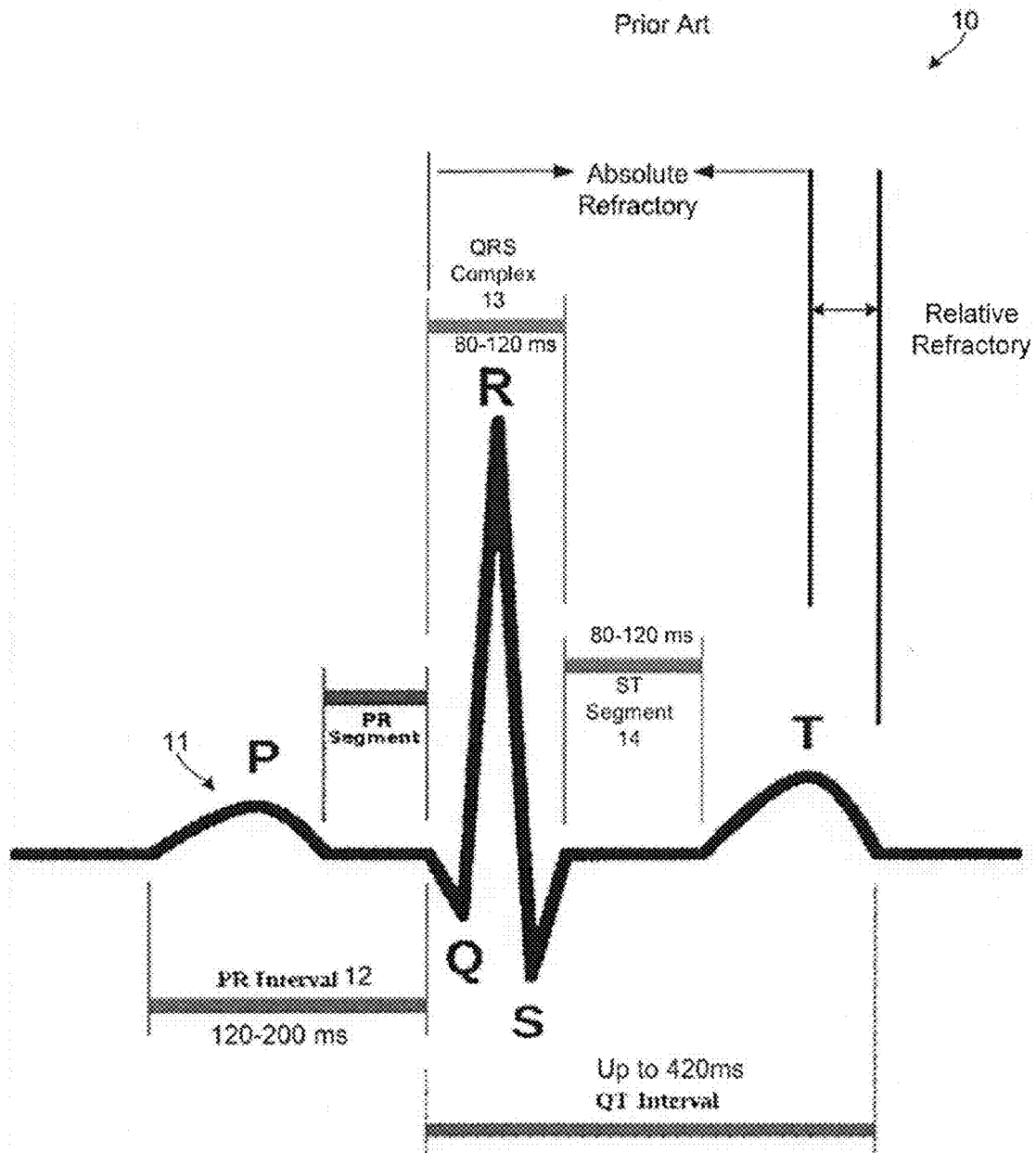
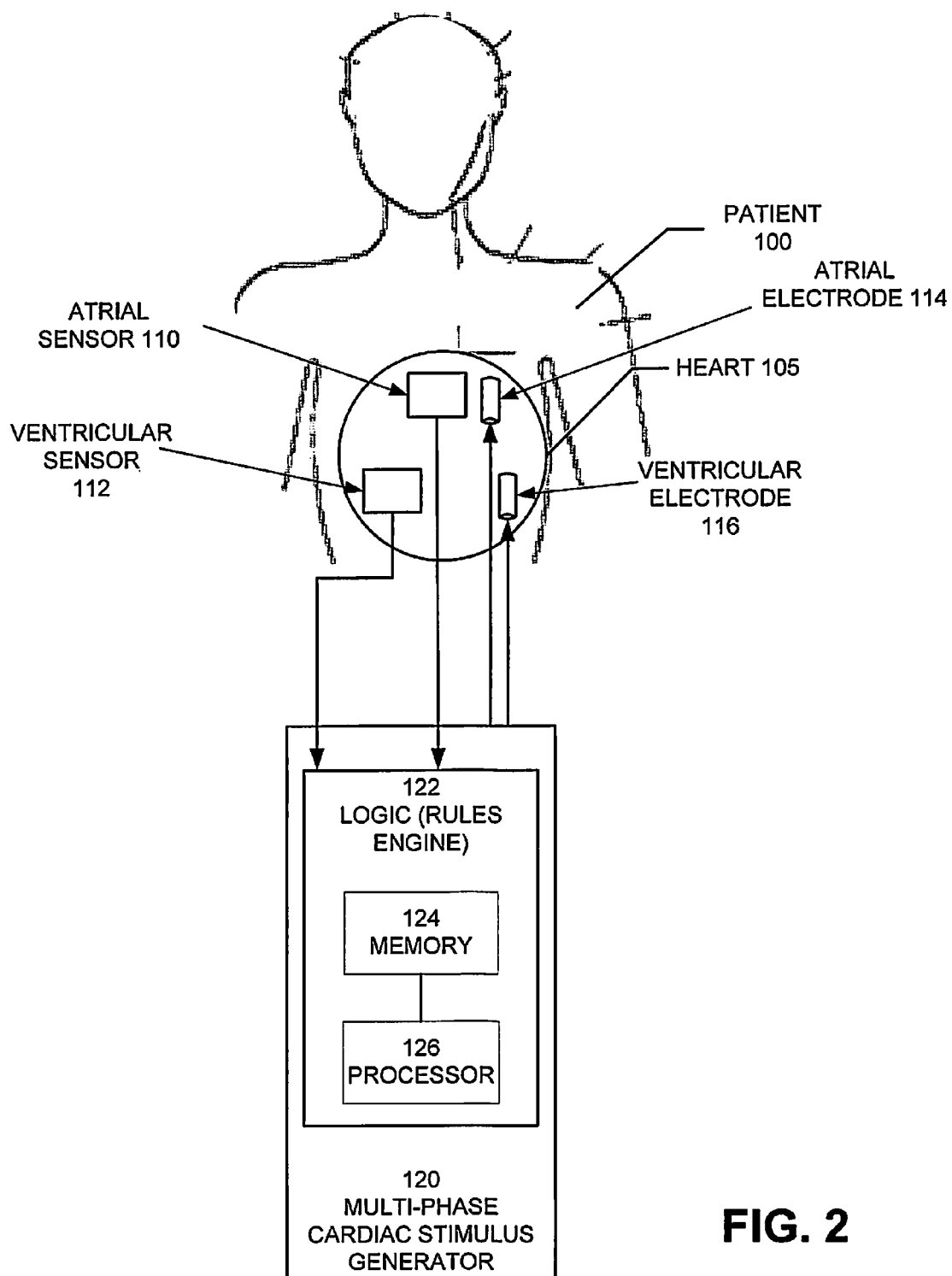


FIG. 1

Prior Art



**FIG. 2**

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SYSTEM AND METHOD FOR TRIGGERING CONDITIONING OF THE HEART USING THE INTRINSIC HEARTBEAT

RELATED APPLICATIONS

This application claims the benefit of priority to U.S. Provisional Patent Application No. 61/826,724, entitled "System and Method for Triggering Stimulation of the Heart Using the Intrinsic Heartbeat" filed May 23, 2013, the entire contents of which are hereby incorporated by reference for all purposes.

BACKGROUND

The heart is divided into the right side and the left side. The right side, comprising the right atrium and ventricle, collects and pumps de-oxygenated blood to the lungs to pick up oxygen. The left side, comprising the left atrium and ventricle, collects and pumps oxygenated blood to the body. Oxygen-poor blood returning from the body enters the right atrium through the vena cava. The right atrium contracts, pushing blood through the tricuspid valve and into the right ventricle. The right ventricle contracts to pump blood through the pulmonary valve and into the pulmonary artery, which connects to the lungs. The blood picks up oxygen in the lungs and then travels back to the heart through the pulmonary veins. The pulmonary veins empty into the left atrium, which contracts to push oxygenated blood into the left ventricle. The left ventricle contracts, pushing the blood through the aortic valve and into the aorta, which connects to the rest of the body. Coronary arteries extending from the aorta provide the heart blood.

The heart's own pacemaker is located in the atrium and is responsible for initiation of the heartbeat. The heartbeat begins with activation of atrial tissue in the pacemaker region (i.e., the sinoatrial (SA) node), followed by cell-to-cell spread of excitation throughout the atrium. The only normal link of excitable tissue connecting the atria to the ventricles is the atrioventricular (AV) node located at the boundary between the atria and the ventricles. Propagation takes place at a slow velocity, but at the ventricular end the bundle of His (i.e., the electrical conduction pathway located in the ventricular septum) and the bundle branches carry the excitation to many sites in the right and left ventricle at a relatively high velocity of 1-2 m/s. The slow conduction in the AV junction results in a delay of around 0.1 seconds between atrial and ventricular excitation. This timing facilitates terminal filling of the ventricles from atrial contraction prior to ventricular contraction. After the slowing of the AV node, the bundle of His separates into two bundle branches (left and right) propagating along each side of the septum. The bundles ramify into Purkinje fibers that diverge to the inner sides of the ventricular walls. This insures the propagation of excitatory waveforms within the ventricular conduction system proceeds at a relative high speed when compared to the propagation through the AV node.

When the heart is working properly, both of its lower chambers (ventricles) pump at the same time as, and in synchronization with, the pumping of the two upper chambers (atria). Up to 40 percent of heart failure patients, however, have disturbances in the conduction of electrical impulses to the ventricles (e.g., bundle branch block or intraventricular conduction delay). As a result, the left and right ventricles are activated at different times. When this happens, the walls of the left ventricle (the chamber responsible for pumping blood throughout the body) do not contract simultaneously, reducing the heart's efficiency as a pump. The heart typically

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responds by beating faster and dilating. This results in a vicious cycle of further dilation, constriction of the vessels in the body, salt and water retention, and further worsening of heart failure. These conduction delays do not respond to antiarrhythmics or other drugs.

Patients who have heart failure may be candidates to receive a pacemaker. A pacemaker is an artificial device to electrically assist in pacing the heart so that the heart may pump blood more effectively. Implantable electronic devices have been developed to treat both abnormally slow heart rates (bradycardias) and excessively rapid heart rates (tachycardias). The job of the pacemaker is to maintain a safe heart rate by delivering to the pumping chambers appropriately timed electrical impulses that replace the heart's normal rhythmic pulses. The device designed to perform this life-sustaining role consists of a power source the size of a silver dollar (containing the battery), and control circuits, wires or "leads" that connect the power source to the chambers of the heart. The leads are typically placed in contact with the right atrium or the right ventricle, or both. They allow the pacemaker to sense and stimulate in various combinations, depending on where the pacing is required.

Either cathodal or anodal current may be used to stimulate the myocardium. The pulses produced by most pacemakers are typically cathodal and excitatory. That is, the cathodal pulse is of sufficient magnitude and length to cause the heart to beat. Cathodal current comprises electrical pulses of negative polarity. This type of current depolarizes the cell membrane by discharging the membrane capacitor, and directly reduces the membrane potential toward threshold level. Cathodal current, by directly reducing the resting membrane potential toward threshold has a one-half to one-third lower threshold current in late diastole than does anodal current.

Anodal current comprises electrical pulses of positive polarity. The effect of anodal current is to hyperpolarize the resting membrane. On sudden termination of the anodal pulse, the membrane potential returns towards resting level, overshoots to threshold, and a propagated response occurs. The use of anodal current to stimulate the myocardium is generally discouraged due to the higher stimulation threshold, which leads to use of a higher current, resulting in a drain on the battery of an implanted device and impaired longevity. Additionally, the use of anodal current for cardiac stimulation was discouraged due to the suspicion that the anodal contribution to depolarization can, particularly at higher voltages, contribute to arrhythmogenesis.

It has been shown that pacing in which a combination of cathodal and anodal pulses of either a stimulating or conditioning nature preserves the improved conduction and contractility of anodal pacing while eliminating the drawback of increased stimulation threshold. The result is a depolarization wave of increased speed. This increased propagation speed results in superior cardiac contraction leading to an improvement in blood flow. Improved stimulation at a lower voltage level also results in reduction in power consumption and increased life for pacemaker batteries.

SUMMARY

In an embodiment, sensors are applied to the heart. The sensors may be used to detect an intrinsic beat of the heart. On sensing an intrinsic heartbeat, a processor determines whether to apply a waveform to the heart based upon predicted strength and regularity of the intrinsic heartbeat and, if a waveform is to be applied, the location and the form of the waveform.

The accompanying drawings, which are incorporated herein and constitute part of this specification, illustrate exemplary embodiments of the invention, and together with the general description given above and the detailed description given below, serve to explain the features of the invention.

DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated herein and constitute part of this specification, illustrate exemplary embodiments of the invention, and together with the general description given above and the detailed description given below, serve to explain the features of the invention.

FIG. 1 is a schematic representation of the electrical activity of a typical heartbeat as is known in the prior art.

FIG. 2 is a schematic representation illustrating a cardiac stimulation device according to an embodiment.

DETAILED DESCRIPTION

As used herein, the term “pulse” refers to a single occurrence of an electrical signal that has a defined shaped and period.

As used herein, the term “waveform” refers to a repeating electrical signal that may include one or more pulses. The pulses that make up the waveform may be the same or may differ in any one of shape, polarity, duration and amplitude. For example, a biphasic waveform may include an anodal pulse and a cathodal pulse. The anodal and cathodal components may differ only in polarity or may differ in shape, polarity, duration and amplitude. Pulses making up a waveform may differ in shape, polarity, duration, and amplitude but be equivalent in power.

As used herein, the term “sub-threshold waveform” refers to a waveform that does not result in stimulating the heart to beat. A waveform may be sub-threshold because the amplitude of the waveform is below an amplitude threshold value necessary to stimulate a heartbeat. A waveform may be sub-threshold because the duration of the waveform is below a duration threshold value necessary to stimulate a heartbeat. A waveform may be sub-threshold because the power of the waveform is below a power threshold value necessary to stimulate a heartbeat.

As used herein, the term “pacing waveform” refers to a waveform that stimulates a heartbeat, results in depolarization and is by definition equal to or greater than a threshold necessary to simulate a heartbeat.

FIG. 1 shows a representative tracing 10 of electrical activity in a typical heartbeat. A P wave 11 represents the wave of depolarization that spreads from the SA node throughout the atria. A period of time from the onset of the P wave to the beginning of a QRS complex is known as the P-R interval 12. The P-R interval 12 represents the time between the onset of atrial depolarization and the onset of ventricular depolarization (typically lasting 20-200 ms). If the P-R interval is >200 ms, there is an AV conduction block, which is also known as a first-degree heart block if the impulse is still able to be conducted into the ventricles.

A QRS complex 13 represents the period of ventricular depolarization, which normally occurs very rapidly (e.g., typically lasting 80-120 ms). If the QRS complex is prolonged, conduction is impaired within the ventricles.

The isoelectric period (ST segment 14) following the QRS complex 13 is the period of time (typically lasting 80-120 ms) at which the entire ventricle is depolarized and roughly cor-

responds to the plateau phase of the ventricular action potential. The ST segment 14 is important in the diagnosis of ventricular ischemia or hypoxia because under those conditions, the ST segment 14 can become either depressed or elevated.

FIG. 2 is a schematic representation illustrating a multi-phase cardiac stimulus generator 120 implanted in a patient according to an embodiment. In an embodiment, one or more sensors sense rhythm and contractions of the patient's heart 105 using at least one of atrial sensing and ventricular sensing, such as at least one of atrial sensor 110 and ventricular sensor 112. The atrial sensor 110 and/or ventricular sensor 112 provide sensor data to a rules engine 122. In an embodiment, the rules engine includes a processor 126 and a memory 124 for storing rules and receiving sensor data. The rules engine 122 may poll the one or more of the atrial sensor 110 and the ventricular sensor 112 to obtain sensor data and to apply the rules to the sensor data in order to determine whether to deliver electrical waveforms to one or more electrodes, and, if electrical waveforms are to be delivered, which of the one or more electrodes is to receive the electrical waveforms. In an embodiment, the one or more electrodes may be an atrial electrode 114 and a ventricular electrode 116, and may provide electrical waveforms to at least one of an atrial chamber and a ventricular chamber of the heart 105. The multi-phase cardiac stimulus generator 120 may generate an anodal waveform, a cathodal waveform, and a biphasic waveform above or below threshold depending on the sensor data and the rules applied by the rules engine 122.

In an embodiment, the memory 124 of the rules engine 122 of the multi-phase cardiac stimulus generator 120 is configured to store waveform data that defines one or more anodal waveforms, cathodal waveforms, and biphasic waveforms. The one or more of the atrial sensor 110 and the ventricular sensor 112 sense for the onset of the intrinsic stimulation of the heart.

In an embodiment, when the onset of intrinsic depolarization is sensed, the processor 126 directs the waveform data to the multi-phase cardiac stimulus generator 120 generator to generate a waveform and to apply the generated to the heart 105 using at least one of the atrial electrode 114 and then ventricular electrode 116. The waveform may be applied for an interval of time, then stopped so as to allow the contractions of the heart to be monitored. If the heart is beating on its own at an acceptable level, then the stimulation may be stopped. Otherwise, the stimulation may be restarted for another interval of time.

In an embodiment, the waveform is an anodal waveform or a biphasic waveform. By allowing a detected intrinsic beat to provide the actual trigger for stimulation (at the same time discontinuing the anodal or biphasic waveform), the heart may be preconditioned. The preconditioning waveform draws less power from the battery (not illustrated) that powers the multi-phase cardiac stimulus generator 120 than a pacing waveform. An additional benefit is that of allowing the heart rate to be controlled by the normal mechanisms of the heart, which can be normally and beneficially affected by usual feedback loops.

In an embodiment, the processor receives information concerning the onset of depolarization, and based upon the strength of the onset of depolarization as measured by the sensors, the processor can determine if stimulation is required, and if stimulation is indicated, provide stimulation based upon the particular characteristics of the patient, the condition of the heart, the medication provided to the patient, and other characteristics to provide the type of stimulation that would be most beneficial.

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In an embodiment, the waveform data stored in memory 124 may include waveform data for anodal waveforms of varying strength (excitatory and non-excitatory) and cathodal waveforms (excitatory and non-excitatory). The processor 126 may be further configured to select a type and strength of a waveform to be administered when the onset of intrinsic stimulation is sensed. For example, the atrial and/or the ventricular sensors 110 and 112 may be pressure sensors. If the pressure data indicates that the pressure within the heart is low, a strong anodal waveform may be selected and applied to the ventricular electrode 116 to strengthen contraction. If the sensor data indicates the pressure within the heart is good, a weaker anodal waveform may be selected. To weaken conduction, a cathodal waveform may be applied to the ventricular electrode 116.

In an embodiment, the ventricular electrode 116 is located adjacent to the septum. Application of stimulation at this location allows lower amplitude cathodal waveforms to be used.

A system and method for triggering stimulation of the heart using the intrinsic heartbeat in an artificially paced heart have been disclosed. It will also be understood that the invention may be embodied in other specific forms without departing from the scope of the invention disclosed and that the examples and embodiments described herein are in all respects illustrative and not restrictive. Those skilled in the art of the present invention will recognize that other embodiments using the concepts described herein are also possible. Further, any reference to claim elements in the singular, for example, using the articles “a,” “an,” or “the” is not to be construed as limiting the element to the singular.

What is claimed is:

1. An apparatus for providing electrical waveforms to a heart comprising:
 - a multiphase cardiac generator;
 - one or more sensors;
 - one or more electrodes implanted on, in, or proximate to at least one of an atrial chamber and a ventricular chamber of the heart;
 - a memory configured to store data from the one or more sensors, rules and waveform data; and

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a processor communicatively coupled to the memory and configured to:

- detect, using the one or more sensors, an occurrence of an intrinsic beat of the heart;
 - apply the rules to the sensor data to determine whether to deliver an electrical waveform to at least one of the one or more electrodes;
 - instruct the multiphase cardiac stimulus generator to generate the electrical waveform from the stored waveform data when it is determined to deliver the electrical waveform to at least one of the one or more electrodes; and
 - deliver the electrical waveform at timing determined from the detected intrinsic beat of the heart,
- wherein the electrical wave-form is a sub-threshold waveform that does not stimulate the heart to beat.
2. The apparatus of claim 1, wherein the electrical waveform is an anodal waveform.
 3. The apparatus of claim 1, wherein the waveform is a cathodal waveform.
 4. The apparatus of claim 1, wherein the one or more sensors include pressure sensors.
 5. The apparatus of claim 1, wherein the processor poles each of the one or more sensors to acquire the data from the one or more sensors, and stores the data in the memory.
 6. The apparatus of claim 1, wherein the processor delivers the electrical waveform for a predetermined time period, stops delivery of the waveform to monitor heart contraction, and to determine whether to resume delivery of the electrical waveform based on the monitored heart contraction.
 7. The apparatus of claim 6, wherein the processor resumes delivery of the electrical waveform when at least one characteristic of the heart contraction is below a predetermined threshold.
 8. The apparatus of claim 6, wherein the processor does not resume delivery of the electrical waveform when characteristics of the hear contraction are above predetermined thresholds.

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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 9,220,904 B2
APPLICATION NO. : 14/285715
DATED : December 29, 2015
INVENTOR(S) : Morton M. Mower

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the specification

Column 1, line 43, change “bundle braides carry” to --bundle branches carry--.

In the claims

Column 6, line 24, claim 5, change “processor poles” to --processor polls--.

Signed and Sealed this
Second Day of August, 2016

A handwritten signature in black ink that reads "Michelle K. Lee". The signature is written in a cursive, flowing style.

Michelle K. Lee
Director of the United States Patent and Trademark Office